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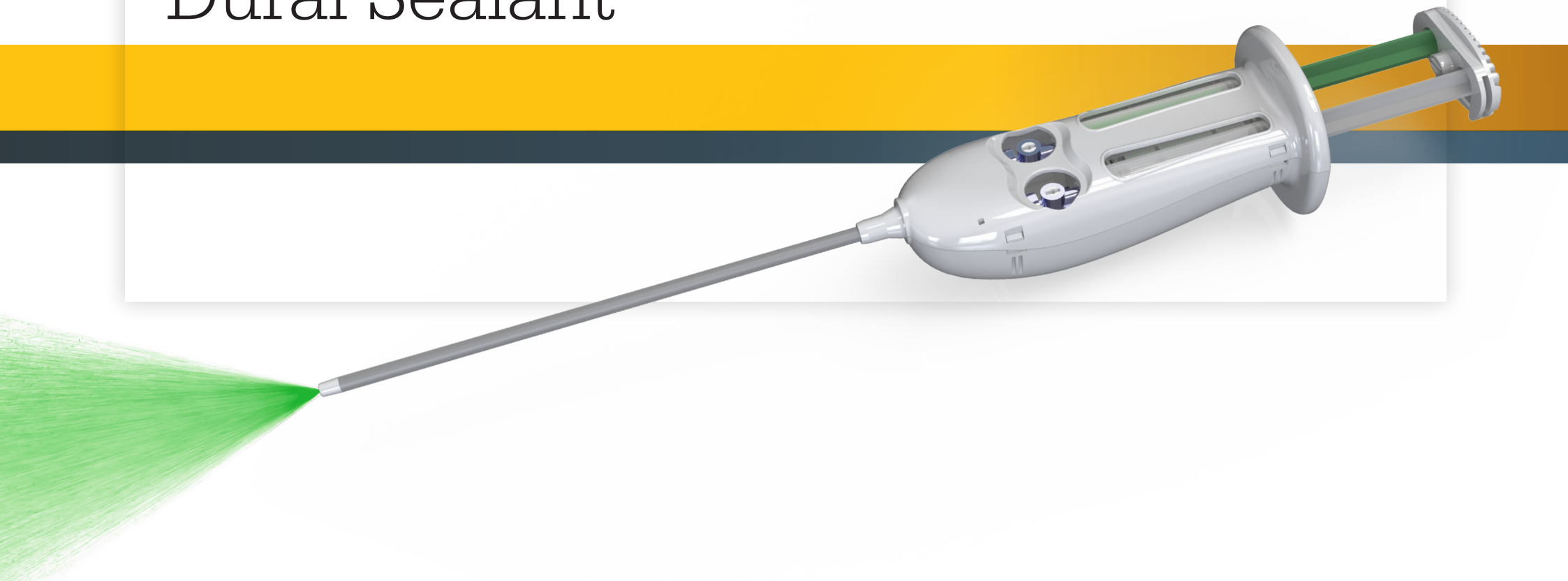
Adherus

AutoSpray ET
Dural Sealant



Adherus AutoSpray ET Dural Sealant

Helps to maintain dural closure during the critical phases of dural healing.*

Product code	Description	Qty
NUS-009	Adherus AutoSpray ET Dural Sealant	5 units

Craniomaxillofacial

This document is intended solely for the use of healthcare professionals. A healthcare professional must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that healthcare professional be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A healthcare professional must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The products depicted are CE marked in accordance with applicable EU Regulations and Directives.

Adherus and Adherus ET are the only FDA-approved hydrogel dural sealant with a patent pending AutoSpray applicator with internal air pump.

*Tew, Jr JM, Strong MJ, West GA, Woo H, Couture DE, Wilson JA, Munoz LF, Rosen CL, Greenlee JD, van Loveren HR, Iantosca M, Baird CJ, Smith M, McGirt M, Parish J, Asher AL. A Pivotal Randomized Clinical Trial Evaluating the Safety and Ectiveness of a Novel Hydrogel Dural Sealant as an Adjunct to Dural Repair. Oper Neurosurg13:204-212, 2017.

CMF-FL-93EN_18715
2018-19320
SDL 01/2019

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Adherus AutoSpray ET Dural Sealant is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial and spinal procedures.

1 Second set time

The Adherus hydrogel sets in approximately one second. It remains where it is applied.

1 Minute setup

Easy setup. Ready to use in one minute.

Two hour window

Once setup, Adherus AutoSpray ET Dural Sealant gives you a two hour window of use.

Go. Stop. Go.

The Adherus AutoSpray ET Dural Sealant applicator allows the surgeon to start and stop as often as required to give complete control of the application.

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The crosslinker with Adherus AutoSpray ET Dural Sealant has been designed with an average of 17 crosslinking endpoints to increase strength and minimise swelling.

0 Infections

Among the subjects treated with Adherus AutoSpray Dural Sealant in a pivotal randomised controlled trial, there were no device related infections and no cases of meningitis.*

Contraindications: Adherus AutoSpray Dural Sealant should not be used in confined anatomical spaces where nerve compression is of concern. The hydrogel may swell by up to 13% of its size in any dimension of 46% by volume after application.

Safety results: A prospective, randomised, controlled, multicentre pivotal trial was conducted to evaluate the safety and effectiveness of Adherus AutoSpray Dural Sealant. The primary endpoint of this study was a composite evaluation of the safety and effectiveness of Adherus AutoSpray Dural Sealant (n=124 subjects) when compared to an active control (n=126). The endpoint results were based on the number of subjects who were free from intra-operative CSF leakage from dural repair after up to two applications of sealant during the Valsalva maneuver, CSF leak/pseudomeningocele during the 120-day follow-up period and unplanned retreatment of the original surgical site within 120 days post-surgery. The overall success rate for the complete case analysis was 91.2% in the Adherus group compared to 90.6% in the control group. Adherus was found to be non-inferior to the control with the non-inferiority margin of 10% (p=0.005). In the early post-surgical period when the sealants are expected to function, the overall success rate at the 14-day follow-up on subjects who completed the visit was 99.1% in the Adherus group compared to the 95.0% in the control group. In addition, the overall success rate at the 45-day follow-up on subjects who completed the visit was 96.6% in the Adherus group compared to 91.9% in the subjects treated with Adherus AutoSpray Dural Sealant, there were no device related deep wound infections and no cases of meningitis. The type and rate of adverse events observed in this study are consistent with the complexity of the surgical procedure and the co-morbid condition of the treated subjects.
Please see Adherus AutoSpray ET Dural Sealant instructions for use for more information.